IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
ERIE DIVISION

UNITED STATES OF AMERICA, *ex rel.* DILBAGH SINGH, M.D., PAUL KIRSCH, M.D., V. RAO NADELLA, M.D., and MARTIN JACOBS, M.D.,	)	
Plaintiffs,	)	CIVIL ACTION NO. 04-186E
v.	)	
BRADFORD REGIONAL MEDICAL CENTER, V & S MEDICAL ASSOCIATES, LLC, PETER VACCARO, M.D., KAMRAN SALEH, M.D., and DOES I through XX,	)	Judge Cohill
Defendants.	)	

RESPONSE TO DEFENDANTS' JOINT MOTION TO DISMISS

Relators Dilbagh Singh, M.D., Paul Kirsch, M.D., V. Rao Nadella, M.D., and Martin Jacobs, M.D. ("Relators") hereby file this response to Defendants' Joint Motion to Dismiss. For reasons discussed below, the motion is wholly without merit and should be denied.

1. The complaint satisfies Rule 9(b).

Rule 9(b) of the Federal Rules of Civil Procedure states in relevant part that "[i]n all averments of fraud . . ., the circumstances constituting fraud . . . shall be stated with particularity." Rule 9(b) does not itself set forth any standard for determining when an averment of fraud is pleaded with sufficient particularity, and the Third Circuit has declined to adopt a rigid rule as to what must be pled, stating that "[c]ourts should . . . apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants." *Rolo v. City Investing Co. Liquidating Trust*, 155

F.3d 644, 658 (3d Cir. 1998). The Third Circuit has held that "[t]he purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim." *Morganroth & Morganroth v. Norris, McLaughlin & Marcus*, P.C., 331 F.3d 406, 414 n. 2 (3d Cir. 2003). Furthermore, as the Court stated in *Christidis v. First Pennsylvania Mortg. Trust*, 717 F.2d 96, 99-100 (3d Cir. 1983):

> In applying the first sentence of Rule 9(b) courts must be sensitive to the fact that its application, prior to discovery, may permit sophisticated defrauders to successfully conceal the details of their fraud. Moreover, in applying the rule, focusing exclusively on its "particularity" language "is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules." 5 C. Wright & A. Miller, Federal Practice and Procedure, Para. 1298 at 407 (1969).

See also In re Craftmatic Securities Litigation, 890 F.2d 628, 645 (3rd Cir. 1990). "Particularly in cases of corporate fraud, plaintiffs cannot be expected to have personal knowledge of the details of corporate internal affairs." *Id*.

"[I]t has been widely held that where the fraud allegedly was complex and occurred over a period of time, the requirements of Rule 9(b) are less stringently applied." *United States ex rel. Johnson v. Shell Oil Company*, 183 F.R.D. 204, 206 (E.D. Tex. 1998); *see also United States ex rel. Butler v. Magellan Health Services, Inc*., 74 F.Supp.2d 1201, 1215 (M.D. Fla. 1999) (specificity requirements less stringent where "the alleged fraud occurred over an extended period of time and consisted of numerous acts"). In addition, Rule 9(b)'s heightened pleading standard has been relaxed if the factual information that is the basis of the claim is particularly within the defendant's knowledge or control. *See Craftmatic*, *supra*, 890 F.2d at 645; *Michaels Building Co. v. Ameritrust Co*., 848 F.2d 674, 680 (6th Cir. 1988); *Moore v. Kayport Package Express, Inc*., 885 F.2d 531, 540 (9th Cir. 1989).

In general, it has been stated that "[t]he relaxed requirement is applied where 'strict application of Rule 9(b) could result in substantial unfairness to private litigants who could not possibly have detailed knowledge of all circumstances surrounding the alleged fraud.'" *Butler*, 74 F. Supp.2d at 1215.

With regard to the False Claims Act in particular, it has been stated that "[a] strict enforcement of Rule 9 would frustrate the purpose of the FCA, so courts allow an exception whereby a plaintiff can plead information that may be available only through discovery." *Id*. "To approach the issue otherwise would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection." *Johnson*, 183 F.R.D. at 207; *see also United States ex rel. McCarthy v. Straub Clinic and Hosp., Inc*., 140 F.Supp.2d 1062, 1068 (D. Haw. 2001) (denying motion to dismiss even though "the Complaint discusses mostly common practices rather than specific dates and times of the submission of false claims").

Without question, the complaint adequately describes the improper compensation paid to V&S and its owners, Dr. Vaccaro and Dr. Saleh (collectively, the "physicians"). Indeed, the complaint attaches a copy of the sham lease agreement, pursuant to which Bradford Regional Medical Center ("BRMC") agreed to pay V&S a greatly inflated price to "rent" a piece of equipment the hospital did not need, did not use, and could have purchased outright for far less than the rental amount, in order to induce continued referrals from the physicians. As alleged in the complaint, and as has been widely recognized, such financial arrangements violate both the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the Stark Act, 42 U.S.C. § 1395nn, thus rendering false all claims submitted as a result of such improper referrals. *See United States ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235 (3d Cir. 2004) (upholding complaint alleging false claims based on violation of Anti-Kickback Statute and Stark Act); *McNutt ex rel. United States v. Haleyville Med. Supplies*, Inc., 2005 U.S. App. LEXIS 19482 (11th Cir.

2005) ("compliance with the [Anti-Kickback] Statute is necessary for reimbursement under the Medicare program").[1]

Defendants' contention that the complaint fails to satisfy Rule 9(b) is thus based not on any alleged failure to describe the improper conduct with requisite specificity, but rather on the fact that the complaint does not identify specific claims for payment submitted for specific patients as a result of the improper kickbacks. This contention is without merit, since identification of such claims is not required by Rule 9(b). The nature and details of the improper kickbacks have been pled with great detail, and Relators have even attached a copy of the sham "lease" agreement entered into by the Defendants. Defendants cannot and do not assert that V&S in fact referred no Medicare or Medicaid patients to BRMC, or that claims for payment were not in fact submitted for such patients, as alleged in the complaint. *See* Complaint, ¶ 4. The falsity of such claims turns not on anything peculiar to such claims, or on anything that would be evident from an examination of the claim forms submitted in connection therewith – rather, such claims are false because of the improper financial arrangements between BRMC and the physicians, which have been pled with great detail. It is those details which are the "circumstances constituting fraud," and which must therefore be pled with particularity under Rule 9(b). Since each and every claim resulting from the improper financial arrangement is false, the identification of specific claims would add nothing to the information already provided by the complaint. Indeed, as discussed below, courts in similar circumstances have upheld similar complaints.

[1] Defendants do not deny that violation of the statutes renders false those claims submitted as a result therof, nor do they assert that the conduct alleged could not support a violation of the Anti-Kickback Statute. They do assert that the complaint does not adequately allege a violation of the Stark Act, although that assertion is without merit, as discussed below.

A. Identification of specific claims is not required.

Numerous courts, when presented with factual situations similar to the present case, have recognized that Rule 9(b) is satisfied even though the complaint does not identify specific claims for payment. For example, in *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp.2d 1017, 1049 (S.D. Tex. 1998), a case concerning a kickback scheme similar to the present case, the court specifically rejected the argument that the relator had to enumerate the specific false claims submitted to the government. Rather, the court held that a description of the "nature of the fraudulent scheme" satisfied Rule 9(b):

> The basic framework, procedures, the nature of the fraudulent scheme, and the financial arrangements and inducements among the parties and physicians that give rise to Relator's belief that fraud has occurred have been alleged with specificity; Plaintiffs are entitled to discovery before being required to list every false claim, its dates, the individuals responsible, and why each patient was not eligible for Medicare.

Id. at 1049. Notably, the failure to identify specific claims in *Thompson* did not affect the reliability of the relator's allegations, since the case was subsequently settled for over $200 million.[2]

Similarly, another court rejected a Rule 9(b) challenge to a complaint which alleged that contractual relationships between doctors and hospitals constituted a kickback scheme that resulted in the filing of Medicare claims. The court stated that:

> [a]lthough no specific dates or West Paces employees are identified, the complaint alleges that the hospital participated in a systematic, fraudulent scheme, spanning the course of twelve years; thus, reference to a time frame and to "West Paces" generally is sufficient. . . . [R]equiring Plaintiff to refer to the specific instances underlying each Medicare and Medicaid claim submission that he claims was fraudulent in his [complaint] would undermine Rule 8's admonishment to keep pleadings simplistic.

United States ex rel. Pogue v. American Healthcorp, Inc., 977 F. Supp. 1329, 1333 (M.D. Tenn. 1997) (internal quotation marks omitted). As with *Thompson*, the failure to identify specific claims for

payment had nothing whatsoever to do with the reliability of the relator's allegations, as demonstrated by the subsequent settlement of the claim.[3]

In a decision from Massachusetts, the district court considered a case where the relator alleged that a drug manufacturer violated the FCA by promoting the use of one of its drugs for "off-label" uses, or uses other than those approved by the Food and Drug Administration. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001). The defendant in that case argued that "the pleading of the basic scheme of fraud or the identification of certain instances of fraudulent conduct does not satisfy Rule 9(b)." *Id*. at 49. The court rejected this argument, noting that:

> [t]his view of Relator's pleading obligation may fit a scenario where the alleged fraud is confined to a small number of transactions about which Relator had knowledge. However, where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.... Although the Relator here does not identify specific prescriptions for Medicaid patients for off-label uses made by doctors in reliance on the fraudulent representations, [the Relator] ... does not reasonably have pre-discovery access to that patient-specific information.

Id. Subsequently, the case settled for $190 million in payments to the federal government and the states.[4]

In *United States ex rel. Downy v. Corning, Inc*., 118 F.Supp.2d 1160, 1173 (D.N.M. 2000), the district court rejected the proposition that, where the complaint adequately describes the defendant's scheme, it is nevertheless deficient unless it identifies particular claims for payment:

> The Complaint adequately describes an allegedly fraudulent scheme, resulting in the submission of false claims for unnecessary medical tests. . . . Relator adequately alleged the general mechanics of the scheme. However, Relator failed to provide a single example of an instance in which a physician was induced to request an unnecessary PAP test, as a result of

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[2] *See* http://www.usdoj.gov/opa/pr/2003/June/03_civ_386.htm

[3] *See* http://www.usdoj.gov/opa/pr/2003/June/03_civ_386.htm (noting $1.5 million settlement of relator's kickback claims).

[4] *See* http://www.taf.org/settlements/PfizerMay2004Settlement.pdf; http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm

> the test requisition forms or Defendants' representations concerning the PAP test. The Court notes some form of limited discovery would probably be necessary to allow Relator to provide such specific examples, if they exist, since information concerning the physicians who requested PSA/PAP tests from Defendants' laboratories is undoubtedly in Defendants' possession rather than the public domain. The Court is of the opinion such arguments are, therefore, more appropriately handled at the summary judgment stage if facts to support Relator's claims fail to materialize. Therefore, the Court will find Relator's complaint satisfies the requirements of Rule 9(b), even without specific examples of false claims submitted to the United States.

(Citations omitted).

In *United States ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 206 (E.D. Tex. 1998), the defendants claimed that the relators were required to "allege facts with excruciating exactness as to the times, locations, and persons, involved in each and every statement plead as well as each statement's contents." In rejecting this position, the district judge observed:

> It is only common sense that the sufficiency of pleadings under Rule 9(b) may depend 'upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading.' *Payne v. United States*, 247 F.2d 481, 486 (8th Cir. 1957). Similarly, it has been widely held that where the fraud allegedly was complex and occurred over a period of time, the requirements of Rule 9(b) are less stringently applied. To approach the issue otherwise would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection.

Id. at 206-07 (citations omitted). The *Johnson* case subsequently resulted in recovery of over $400 million from the various defendants.[5]

All of these cases recognize that it is not necessary that particular claims be identified in order to satisfy Rule 9(b). Indeed, such a rule would serve only to insulate from liability companies that violate the statute on a massive scale, since no single relator would have all the information necessary to identify the particular claims involved – although the defendant would certainly have such information.

The Third Circuit has specifically cautioned courts to be sensitive to this fact. *See Christidis v. First Pennsylvania Mortgage Trust*, 717 F.2d 96, 99-100 (3d Cir. 1983) (courts should be "sensitive to the fact that [Rule 9(b)'s] application, prior to discovery, may permit sophisticated defrauders to successfully conceal the details of their fraud").

The present case is similar to many of the above cases in that the fraudulent conduct at issue – whether improper kickbacks or an improper marketing scheme – is conduct that does not relate to individual specific claims. For example, Relators are not alleging that a specific test performed on a specific patient was medically unnecessary, as alleged by the relator in *United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301 (11th Cir. 2002). Nor do Relators allege that the Defendants submitted claims for services that were not provided, or used improper billing codes that resulted in greater reimbursement than was warranted, as was alleged in *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.F.3d 220 (1st Cir. 2004). Rather, as in *Thompson* and *Pogue*, Relators allege that BRMC entered into an improper financial relationship with V&S and the physicians, and that every claim submitted as a result of a referral from the physicians is thus tainted. The falsity of the claims thus does not turn on anything specific to the particular claims themselves, but rather on the improper inducements paid to the referring physicians. It is these financial inducements that are the "circumstances constituting fraud," and these inducements have been alleged with great specificity. While the exact number of improper referrals might be an issue for trial, Defendants cannot and do not deny that the physicians did in fact make referrals to BRMC, as alleged in the complaint. *See* Complaint, ¶ 4 (alleging that physician referred Medicare and Medicaid patients to BRMC, and that

[5] *See* http://www.usdoj.gov/opa/pr/2001/February/052civ.htm .

BRMC submitted claims to Medicare and Medicaid and obtained hundreds of thousands of dollars of reimbursements).

As the Third Circuit has held, "[t]he purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim." *Morganroth & Morganroth v. Norris, McLaughlin & Marcus*, P.C., 331 F.3d 406, 414 (3d Cir. 2003). Defendants have been given abundant notice of the misconduct with which they are charged. Information about the specific patients referred by the physicians is information that is manifestly within the possession of the Defendants, and requiring Relators to identify such patients in their complaint does nothing to provide Defendants additional notice.

Nor would such a requirement advance the cause of justice, or serve to deter only "spurious" claims – indeed, as discussed above, the defendants in *Thompson*, *Pogue*, *Franklin*, and *Johnson* all argued that identification of specific claims was necessary to satisfy Rule 9(b), and ended up paying $800 million between them when the courts rejected such a requirement. Had the courts accepted the defendants' proposed interpretation of Rule 9(b) in such cases, their massive frauds upon the government would have gone undiscovered, future relators would have been deterred from coming forward, and corporate fraudsters would have been emboldened to continue their fraud. Indeed, had the courts accepted such a rule, corporations would have learned that they could effectively insulate themselves from FCA liability by keeping their billing departments separate from their marketing and professional departments. Although the marketing or professional personnel might have knowledge of improper financial arrangements or marketing practices, they would not have access to the patient-specific billing records, and would thus be unable to identify specific claims submitted as a result of such practices, although they are aware such that claims were in fact submitted. Conversely, the billing clerks might have access to patient-specific claims, but would have no way of knowing that an improper

kickback had been paid to obtain the referral. Because any one individual would be unlikely to have his hands on "both ends of the elephant," Defendants could rest assured that their schemes would go unmentioned or unpunished.

Quite clearly, requiring a plaintiff to identify specific claims for payment, when (i) there is nothing about those specific claims which would be a "circumstance constituting fraud," other than the improper financial arrangements which have already been pled with specificity; (ii) the information regarding those specific claims is manifestly within the possession of defendants, although typically concealed from the plaintiffs[6]; and (iii) the only way the defendants could escape liability on the merits would be if they submitted no claims based on referrals from physicians who received kickbacks, a fact which, if true, would be the easiest thing in the world for a defendant to demonstrate in the first week of discovery – requiring pre-discovery identification of specific claims under those circumstances would

[6] Defendants implausibly assert in this case that Relators could have gotten claim-specific information from the government or a third party in some manner – although in the very next breath they say that, if Relators had done so, their claims would be barred by the public disclosure rule. Defendant's Brief, p. 8 and fn. 2. It is difficult to see how a plaintiff can be said to have access to information so as to comply with Rule 9(b), if the very act of obtaining such information would prohibit the plaintiff from bringing a claim. Indeed, Defendants' argument on this point was squarely rejected by the Court in *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.F.3d 220 (1st Cir. 2004), a case upon which Defendants rely for other purposes. *Id*. at 230 (argument that information is within possession and control of defendants "cannot be answered by the court's suggestion that [relator] could have obtained that information from the government prior to filing his complaint"). Moreover, as a factual matter, it is untrue to suggest that a party may utilize the Freedom of Information Act to obtain patient-specific information, since "FOIA's disclosure requirements do not apply to 'personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.' 5 U.S.C. § 552(b)(6)." *U.S. Dept. of Defense v. Federal Labor Relations Authority*, 510 U.S. 487, 494-495, 114 S.Ct. 1006, 1012, 127 L.E.2d 325 (1994).

serve no legitimate purpose whatsoever. Although such a requirement would indeed deter the filing of spurious claims, that would only be because it deterred the filing of all claims, something Rule 9(b) was not intended to accomplish. The court should decline to convert Rule 9(b) from a gatekeeper, designed to keep out spurious claims, into a brick wall, which indiscriminately blocks both the meritorious and the spurious, for reasons having nothing to do with the merits.

B. *Clausen* doesn't require identification of claims.

Perhaps the case most often cited for the proposition that identification of specific claims for payment is necessary to satisfy Rule 9(b) is *United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301 (11th Cir. 2002). However, far from requiring that specific claims be identified in the complaint, *Clausen* expressly rejected such a requirement, requiring only that the complaint contain "some indicia of reliability" to support the allegation that false claims were submitted:

> Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government. As in *Cooper*, and as with every other facet of a necessary False Claims Act allegation, if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government.

Clausen, 290 F.3d at 1311 (emphasis added). The Court did not purport to limit the ways in which a relator might provide such "indicia of reliability," although it suggested some ways in which such reliability might be demonstrated. In discussing the complaint at issue, the Court noted that:

> No amounts of charges were identified. No actual dates were alleged. No policies about billing or even second-hand information about billing practices were described, other than to state that electronic HCFA Form 1500s with medical test codes were used. No copy of a single bill or payment was provided.

Id. at 1312. In a corresponding footnote, the Court stated that:

> this discussion merely lists some of the types of information that might have helped Clausen state an essential element of his claim with particularity but does not mandate all of this information for any of the alleged claims. Although Clausen has provided none of these items of information here, some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)."

Id. at 1312 n. 21 (emphasis added). Thus, *Clausen* rejected a rigid test for determining compliance with Rule 9(b), and in particular rejected the proposition that specific claims must be identified in order to satisfy Rule 9(b). Rather, the Court held that reliability could be demonstrated by information such as "policies about billing or even second-hand information about billing practices." The key point is simply that there must be "some indicia of reliability" as to a relator's allegations that claims were submitted in connection with the described conduct.

In a subsequent unpublished opinion, *United States ex rel. Hill v. Morehouse Medical Associates, Inc*., 2003 WL 22019936 (11th Cir. 2003), the Eleventh Circuit confirmed this interpretation of *Clausen*, holding that the complaint satisfied Rule 9(b) even though it did not identify specific claims for payment submitted by the defendant. In keeping with *Clausen*'s flexible approach, the Court construed *Clausen* as simply requiring that "to comply with Rules 8 and 9(b), 'some indicia of reliability must be given in the complaint to support the allegation of' fraud." *Id*. at *3, *quoting Clausen*, 290 F.3d at 1311. The Court expressly rejected the proposition that identification of specific claims for payment was necessary to provide such indicia, holding that:

> [f]ailure to allege patient names and the exact dates that claims were submitted to the government . . . is not fatal to a claim under the FCA. Our precedent requires only that "a plaintiff … plead … the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." [*Clausen*], 290 F.3d at 1310 (internal quotation marks omitted). Under the facts of this case, the question of "who engaged in" the fraudulent acts is answered by the names of the MMA employees and physicians who altered the CPT and diagnosis codes, not the patient names. *Id*. (internal quotation marks omitted). Additionally, to require Hill to provide the exact dates that claims were submitted to the government would require that she violate patient confidentiality by copying private records. As we are not prepared to encourage violations of patient confidentiality, we find that Hill need not provide

the exact dates that claims were submitted to the government to satisfy Rule 9(b).

Id. at n. 8 (emphasis added). Thus, not only is it incorrect to assert that *Clausen* requires the identification of specific claims, but *Clausen* and *Hill*, taken together, emphatically reject such a proposition.[7]

For the above reasons, the Court should reject Defendants' assertions that the complaint fails to satisfy Rule 9(b).[8]

2. Defendants' arguments regarding Stark are without merit.

Defendants' assertion that the complaint does not state a claim for violation of the Stark Act is patently absurd, and wholly unsupported by any citation to authority. Defendants first assert that any compensation arrangement between BRMC and the individual physicians must necessarily be an "indirect" one, since the sham lease arrangement was between BRMC and V&S, rather than directly with the physicians. Defendants then assert that, because the compensation under the sham lease is fixed, and does not vary based upon the referrals made to the hospital, it cannot constitute an "indirect compensation arrangement" under the relevant C.F.R. provisions.[9]

This "argument" – which is notably devoid of any citation to case law – fails for the simple fact

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[7] It should also be noted that *Clausen* was a 2-1 decision, with a vigorous dissent from Judge Barkett, who believed that the complaint satisfied Rule 9(b), and that the majority's decision improperly "asks for proof." *Clausen*, 290 F.3d at 1317 (Barkett, J., dissenting). The majority decision in *Clausen* has also been criticized and rejected by other courts. *See United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 269 (D.D.C. 2002) (noting that "This Court agrees with the dissent [in *Clausen*]."

[8] Defendants' assertion that the complaint fails to state a claim for conspiracy is nothing more than a restatement of its argument that the complaint fails to satisfy Rule 9(b), and should be rejected for the same reasons. The complaint clearly provides a factual basis for the allegation of a conspiracy, since it alleges the improper financial remuneration flowing from BRMC to V&S and the physicians.

that the relevant provisions do not require a compensation arrangement to vary with the volume or value of referrals made by the physician. Rather, the provision at issue states that an indirect compensation arrangement exists if:

> [t]he referring physician … receives aggregate compensation . . . that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

42 C.F.R. 411.354(c)(2)(ii) (emphasis added). Thus, it is not necessary that the compensation vary with the volume or value of referrals, but is sufficient if it "otherwise reflects" such volume or value. Quite plainly, an arrangement "otherwise reflects" such value if it takes into account the expected value of the referrals to be provided by the physician. Indeed, Defendants' construction would read the words "otherwise reflects" out of the regulation, and open an enormous loophole for clever parties to exploit. One could easily imagine a hospital saying, "I can't pay you $50 for each referral, but I expect that you'll refer 10 patients a month, so we'll just agree on a flat fee of $500 per month." While such an arrangement might not "vary with" the number of referrals, it certainly "otherwise reflects" such referrals, and is clearly intended to be foreclosed by the Stark Act.

Moreover, Defendants' unsupported interpretation would also be contrary to the express language of the enabling statute, which broadly defines "compensation arrangement" as "any arrangement involving any remuneration between a physician … and an entity other than an arrangement involving

[9] Of course, Defendants' argument on this point only relates to the alleged violation of the Stark Act. Defendants do not even assert that the allegation regarding violation of the Anti-Kickback Statute is insufficient to state a claim under Rule 12(b)(6) for violation of the False Claims Act.

only remuneration described in subparagraph (C)," and defines "remuneration" to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(A), (B) (emphasis added). Indeed, the statute itself recognizes that sham equipment lease agreements may violate the statute, and provides that such agreements are proper only if, among other things, "the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner which takes into account the volume or value of any referrals or other business generated between the parties." 42 U.S.C. § 1395nn(e)(1)(B)(iv) (emphasis added). Notably, Congress did not use the words "vary with," but rather used the words "takes into account," demonstrating that a rental amount which contemplates the anticipated value of the referrals during the lease term is equally prohibited.

On a more general level, Congress was plainly cognizant of the possibility that parties might try to evade the self-referral prohibitions by entering into "sham" lease arrangements, and intended to proscribe such arrangements. Under Defendants' interpretation, however, such arrangements would be impermissible only if the lease agreement stated on its face that the rental amount was directly tied to the number or value of illegal referrals made by the lessor-physicians. Since it is almost impossible to conceive of any defendant who is (i) smart enough to enter into a sham lease arrangement intended to disguise improper compensation, while at the same time (ii) foolish enough to expressly state in the lease that the rental amount is directly tied to the number or value of referrals the statute is designed to prohibit, Defendants' construction of the C.F.R. provision would lead to a frustration of the Congressional intent.

On a motion to dismiss, the allegations of the complaint are to be taken as true, and the complaint is to be "'view[ed] . . . liberally giving plaintiffs the benefit of all inferences which fairly may be drawn therefrom.'" *Wilson v. Rackmill*, 878 F.2d 772, 775 (3d Cir. 1989). "Dismissal for failure to state a claim is appropriate only if it 'appears beyond doubt that plaintiff can prove no set of facts in support of his claim which would entitle him to relief.' *Conley v. Gibson*, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957)." *Worldcom, Inc. v. Graphnet, Inc*., 343 F.3d 651, 653 (3d Cir. 2003). At this stage of the litigation, it cannot be said, much less beyond doubt, that Relators can prove no set of facts showing that the lease arrangement violates the Stark Act. Accordingly, Defendants' motion to dismiss on this issue must be denied.[10]

3. <u>Relators should be allowed to amend</u>.

Defendants' assertion that the complaint should be dismissed without leave to amend is absurd. As discussed above, Relator believes that the complaint fully complies with Rule 9(b) in its current form and otherwise states a claim. However, to the extent that the Court disagrees, Relator should certainly be given leave to address any deficiencies the Court might find. Indeed, the Third Circuit has consistently held that, before dismissing a complaint for failure to state a claim, the district court must give a plaintiff

[10] As to Relators' assertion that BRMC failed to properly reflect the improper remuneration on its cost report, Defendants speculate that such report was likely submitted after the filing of the complaint (although they notably do not deny the substance of Relators' allegations). Of course, Defendants do not introduce any evidence on this point. This is more properly a matter for summary judgment after the development of evidence, rather than for a motion to dismiss. In any event, regardless of the cost report issue, the fact remains that each and every claim for payment submitted as a result of an improper referral constitutes a false claim.

an opportunity to amend his complaint to cure any defects. As the Court noted in *Shane v. Fauver*, 213 F.3d 113, 116 (3d Cir. 2000):

> In *Borelli v. City of Reading*, 532 F.2d 950 (3d Cir. 1976), this court stated that a district court should use the following procedure in dismissing a complaint for failure to state a claim:
>
> > We suggest that district judges expressly state, where appropriate, that the plaintiff has leave to amend within a specified period of time, and that application for dismissal of the action may be made if a timely amendment is not forthcoming within that time. If the plaintiff does not desire to amend, he may file an appropriate notice with the district court asserting his intent to stand on the complaint, at which time an order to dismiss the action would be appropriate.

This principle was confirmed in *Shane*, where the Court held that "dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." *Shane*, 213 F.3d at 117. *See also District Council 47 v. Bradley*, 795 F.2d 310 (3d Cir.1986) (holding that if the complaint was deficient, the District Court should have followed the procedure outlined in *Borelli* and granted leave to amend even though the plaintiff never sought leave to amend); *Jame Fine Chems. Co. v. Hi-Tech Pharmacal Co.*, 44 Fed. Appx. 602, 605 (3d Cir. 2002).

In the present case, there is no assertion of bad faith, undue delay, or prejudice, and there is no reason to believe that Relators would be unable to cure any defects the Court might find in the complaint. Indeed, under Fed. R. Civ. P. 15(a), Relators have the absolute right to amend one time before Defendants file a responsive pleading. *See Shane*, *supra* at 115 ("in the typical case in which a defendant asserts the defense of failure to state a claim by motion, the plaintiff may amend the complaint once 'as a matter of course' without leave of court"). Accordingly, if the Court finds that Relators' complaint is defective in any way, Relator is entitled to at least one opportunity to amend. *See also Hemphill v. Meyerson*, 65 Fed. Appx. 776, 781 (3d Cir. 2003) (noting that "complaints dismissed under Rule 9(b) are almost always dismissed with leave to amend") (internal quotation marks omitted).

CONCLUSION

For the reasons stated above, Defendants' motion to dismiss should be denied.

This 11th day of October, 2005.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
ERIE DIVISION

UNITED STATES OF AMERICA, *ex rel.* DILBAGH SINGH, M.D., PAUL KIRSCH, M.D., V. RAO NADELLA, M.D., and MARTIN JACOBS, M.D.,	)	
Plaintiffs,	)	CIVIL ACTION NO. 04-186E
v.	)	
BRADFORD REGIONAL MEDICAL CENTER, V & S MEDICAL ASSOCIATES, LLC, PETER VACCARO, M.D., KAMRAN SALEH, M.D., and DOES I through XX,	)	Judge Cohill
Defendants.	)	

CERTIFICATE OF SERVICE

I hereby certify that on this 11tht day of October, 2005, I caused a copy of the Plaintiffs' RESPONSE TO DEFENDANTS' JOINT MOTION TO DISMISS to be filed electronically and/ or served by first-class mail, postage prepaid, on:

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